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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,888	12/21/2001	William Canfield	203515US77	5416

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/27/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,888

Applicant(s)

CANFIELD ET AL.

Examiner

Elizabeth Slobodyansky

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1652 °

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-55 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a method of phosphorylating a protein using soluble GlcNAc phosphotransferase, classified in class 435, subclass 41.
- II. Claims 20 and 21, drawn to a method of phosphorylating a protein using soluble GlcNAc phosphotransferase made by a host cell and comprising the mixture of subunits, classified in class 435, subclass 41.
- III. Claims 22, 26 and 28-37, drawn to a GlcNAc phosphotransferase, classified in class 435, subclass 194.
- IV. Claims 23-25, 27 and 38-51, drawn to a DNA encoding GlcNAc phosphotransferase, a vector and host cell containing the same and a method of making a GlcNAc phosphotransferase, classified in class 435, subclass 194.
- V. Claim 52, drawn to a phosphorylated protein obtained by the method of claim 1, classified in class 435, subclass 183.
- VI. Claim 53, drawn to a phosphorylated protein obtained by the method of claim 17, classified in class 435, subclass 183.

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- VII. Claim 54, drawn to a method of treating a patient with a lysosomal hydrolase modified by a GlcNAc phosphotransferase of claim 26 or 32, classified in class 424, subclass 94.6.

Inventions III and IV are patentably distinct because a GlcNAc phosphotransferase and a DNA encoding thereof are different compounds each with its own chemical structure and function, and they have different utilities. The DNA molecules of inventions IV are not limited in use for the production of a GlcNAc phosphotransferase of invention III and can be used as hybridization probes, and a GlcNAc phosphotransferase of invention III can be obtained by a materially different method such as by the biochemical purification or chemical synthesis.

Inventions III, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally and functionally different enzymes and proteins. Therefore, where structural identity is required, such as for pharmacological effects and production of antibodies, the different sequences have different effects.

Inventions (III and I) and (IV and II), respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

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practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case a GlcNAc phosphotransferase of invention III can be used to induce antibodies and in *in vitro* screening for inhibitors thereof. A DNA of invention IV can be used as a hybridization probe.

Inventions I and V-VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a phosphorylated protein can be obtained by chemical methods or using different enzymes.

Methods of inventions I and II are patentably distinct as employing different compounds such as a GlcNAc phosphotransferase and a DNA and comprising different steps.

A phosphorylated proteins of inventions V and VI and hydrolases used in invention VII are not necessarily have the same compositions and/or structures as being obtained by different modification methods.

If invention VII is drawn to a method of use of a hydrolase encompassed by invention V or VI, the invention V-VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

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shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product can be used to induce antibodies.

A telephone call was made to Dr. Daniel Pereira on February 14, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

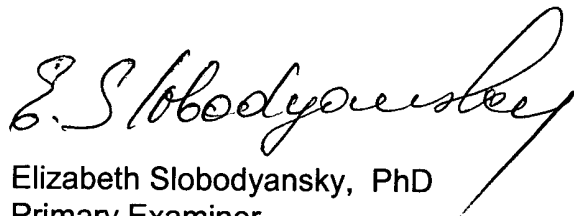
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in dark ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

February 24, 2003